

REMARKS

Reconsideration of this application and withdrawal of the rejections set forth in the non-final Office Action mailed September 3, 2009, is requested in view of this amendment and the following remarks. Claims 1-27 and 36-37 were pending and at issue prior to this amendment. Claims 1, 15, 19, and 72 have been amended herein. The claims as amended are fully supported by the original specification as filed.

I. Objection to the Drawings

The drawings were objected because Fig. 4 failed to include the reference numeral “50” referred to in the description at page 10, line 15 that states that Fig. 4 has sheath 50. Fig. 4 has been amended to add the reference numeral 50 to refer to the sheath. No new matter has been added. A Replacement Sheet is attached hereto with the added reference numeral 50, and an annotated sheet showing the changes to the original drawing sheet. Thus, this objection should be withdrawn.

II. Rejection of Claims 1-14, 24-27 and 36 under 35 U.S.C. Section 112, first paragraph

Claims 1-14, 24-27 and 36 stand rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the description of the marker wire being “permanently” coupled to the medical device was not found in the specification. Without acquiescing to the rejection, and expressly reserving the right to pursue claims having such limitation in related application, Applicant has amended the claims to remove the term “permanently,” thereby overcoming this rejection.

III. Rejection of Claims 9-12 and 14 under 35 U.S.C. Section 112, first paragraph

Claims 9-12 and 14 stand rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that it is not described

in the specification how the marker wire can be permanently coupled to the medical device of a stent or an expansion balloon. The Examiner also cites to certain argument in the Appeal Brief filed April 14, 2009 that a person of ordinary skill in the art would recognize that a marker placed directly on a stent or expansion balloon would interfere with the stent's and/or expansion balloon's ability to expand.

First of all, Applicant has amended claims 9-12 and 14 to remove the requirement that the marker be “permanently” coupled to the medical device. Moreover, claims 9-12 do NOT require that the marker be coupled “directly” to a stent or expansion balloon of the medical device. Indeed, Applicant describes that the marker may be coupled to a sheath of the medical device. Although dependent claims 9-12 and 14 recite that the medical device comprises a stent and/or a balloon, this claim language is in the open form (“comprising” form), and therefore these limitations do not preclude the medical device from having additional components, such as a sheath. Furthermore, the specification explicitly describes embodiments of wire marker to allow shifting of the position of the markers during expansion of the medical device (see e.g. page 14, line 27 – page 15, line 33).

In addition, the limitation of coupling the wire marker to a stent or balloon were subject matter of original claims 9-12 and 14 in the specification as failed. As such, the claims provide written description for themselves, and cannot properly be rejected as failing to comply with the written description requirement (see MPEP).

Therefore, claims 9-12, and 14 comply with the written description requirement, and this rejection should be withdrawn.

IV. Rejections under 35 U.S.C. Section 102

Claims 1-6, 12, 13, 24 and 25 stand rejected under 35 U.S.C. § 102(e), as being

anticipated by Hyde (U.S. Patent No. 6,957,098). Applicant submits that this rejection should be withdrawn because Hyde does not disclose or teach the claimed apparatus comprising a medical device and a marker wire coupled to said medical device, the medical device having a length and a longitudinal axis, the marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area, the closed area having a length that is less than the length of the medical device, a first directional indicator coupled to said medical device, the first directional indicator comprising a first portion of a symbol; a second directional indicator coupled to said medical device offset from said first directional indicator, the second directional indicator comprising a second portion of the symbol; wherein images of said first and second directional indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. In order to sustain a rejection for anticipation, each and every element of the claim must be found, either expressly or inherently, in a single prior art reference, and arranged as required by the claim. *See* MPEP § 2131; *In re Bond*, 910F.2d 831 (Fed. Cir. 1990).

Instead, Hyde discloses a marker for interventional devices comprising an RF oscillation circuit and a pressure sensitive transducer which can vary the transmission frequency of the RF signal based on the adjustable pressure on the transducer. The system then detects the RF signal in order to fix the location of the marker. Hyde is wholly inapplicable to the present invention which utilizes a marker visible to an imaging device, not an RF receiver.

Moreover, independent claim 1 has been amended to recite first and second directional indicators wherein their images connect to form a symbol when the medical device is in a proper

rotational orientation. It is very clear that Hyde does not disclose such first and second directional indicators wherein their images connect to form a symbol when the medical device is in a proper rotational orientation.

Accordingly, claim 1 is not anticipated by Hyde. Claims 2-6, 12, 13, 24 and 25 depend from claim 1, or an intervening claim, and are not anticipated by Hyde for at least the same reasons applicable to claim 1. Therefore, this rejection should be withdrawn as to those claims.

Claims 1-5, 8-11, and 14 stand rejected under 35 U.S.C. Section 102(b) as being anticipated by Lombardi (U.S. Patent No. 5,824,042). Like Hyde discussed above, Lombardi similarly does not disclose or teach the claimed apparatus comprising a medical device and a marker wire coupled to said medical device, the medical device having a length and a longitudinal axis, the marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area, the closed area having a length that is less than the length of the medical device, a first directional indicator coupled to said medical device, the first directional indicator comprising a first portion of a symbol; a second directional indicator coupled to said medical device offset from said first directional indicator, the second directional indicator comprising a second portion of the symbol; wherein images of said first and second directional indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device.

As with Hyde, Lombardi does not disclose such first and second directional indicators wherein their images connect to form a symbol when the medical device is in a proper rotational orientation. Thus, claims 1-5, 8-11, and 14 are not anticipated by Lombardi, and this rejection

should be withdrawn.

V. Rejections under 35 U.S.C. Section 103

Claims 1-6, 13, 24, 25 and 37

In the Office Action, the Examiner rejected claims 1-6, 13, 24, 25 and 37 under 35 U.S.C. Section 103(a) as being obvious over Makower '311 (U.S. Patent No. 6,579,311) in view of Makower '875 (U.S. Patent No. 6,302,875). Applicant respectfully submits that this rejection should be withdrawn because Makower '311 in view of Makower '875 does not disclose, suggest or otherwise render obvious the claimed apparatus comprising a medical device and a marker wire coupled to said medical device, the medical device having a length and a longitudinal axis, the marker wire extending such that a first portion of the marker wire extends in a circumferential direction about the longitudinal axis of the medical device and a second portion of the marker wire extends in a direction parallel to the longitudinal axis of the medical device, at least a portion of the marker wire defining the perimeter of a closed area, the closed area having a length that is less than the length of the medical device, a first directional indicator coupled to said medical device, the first directional indicator comprising a first portion of a symbol; a second directional indicator coupled to said medical device offset from said first directional indicator, the second directional indicator comprising a second portion of the symbol; wherein images of said first and second directional indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device.

While the Supreme Court in *KSR International Co. v. Teleflex Inc.* ("KSR")¹ held that there are no rigid rules for determining obviousness, the Court reaffirmed that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some

articulated reasoning with some rational underpinnings to support the legal conclusion of obviousness.”² As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. §103 is stated in *Graham v. John Deere Co.*³ Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art; and
- (4) Considering objective evidence (secondary considerations) indicating obviousness or non-obviousness.

Although the Court in KSR rejected rigid preventative rules in making an obviousness inquiry, the Court reaffirmed that there must be some articulated rationale in order to modify or combine the teachings of multiple references in making an obviousness rejection.⁴ Furthermore, the combined teachings of the prior art must at least result in the Applicant’s claimed invention.

Therefore, to establish a *prima facie* case of obviousness, the Examiner must establish three basic criteria: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in

¹ 550 U.S. ___, ___ (2007)

² 550 U.S. ___, ___ (2007)

³ 550 U.S. ___, ___ (2007)

applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is improper to pick and choose among features and elements found in the prior art references in a hindsight reconstruction of Applicants' claimed invention. *See e.g., In re Jones*, 958 F.2d 347, 350-51 (Fed. Cir. 1992); *In re Fritch*, 919 F.2d 720 (Fed Cir. 1990) ("It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious"). Furthermore, it is improper to combine the teachings of references where the references teach away from the asserted combination. MPEP § 2145. Applicant submits that the Examiner's obviousness rejection cannot be sustained consistent with these well-established requirements for obviousness.

Although Makower '311 appears to disclose a marker which can be used to determine the rotational orientation of a medical device using an imaging device, it does not disclose the Applicant's claimed first and second directional indicators wherein the images of the indicators connect to form the image of a symbol when positioned in the proper rotational orientation. Instead, the marker of Makower '311 forms in image of a solid circle concentrically aligned with an open circle. As a result, the images of the marker of Makower '311 do NOT "connect" as required by Applicant's claimed first and second directional indicators. This is a significant and critical distinction, because the "connecting" images can provide for a much easier to read and accurate indicator. Similarly, the alignment of overlapping lines such as in Figs. 3a and 3b of Makower '311 does not provide for the easy to read and accurate indicator of Applicant's claimed invention. For example, the lines of the markers of Figs. 3a and 3b may be slightly misaligned, but would still appear as a single, solid line. Furthermore, the use of simple lines are NOT a "symbol" as required by Applicant's claimed invention. A symbol is much less

⁴ 550 U.S. ___, ___ (2007)

susceptible to being confused with image artifacts than simple lines.

Makower '875 does not overcome the deficiencies of Makower '311, just discussed. Therefore, claims 1-6, 13, 24, 25 and 37 are not obvious over Makower '311 in view Makower '875, and this rejection should be withdrawn.

Claim 27

Claim 27 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '311 in view of Makower '875 and further in view of Plaia (U.S. Patent No. 6,497,711). This rejection should be withdrawn for the same reasons as the obviousness rejection of claim 1, i.e., Plaia does not overcome the deficiencies of Makower '311 and Makower '875, as described above. Specifically, Plaia does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device.

Accordingly, claim 27 is not obvious over Makower '311 in view of Plaia, and this rejection should be withdrawn.

Claims 1-7, 12, 15, 16, 18-20, 23-25 and 37

Claims 1-7, 12, 15, 16, 18-20, 23-25 and 37 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875. This rejection should be withdrawn for the same reasons as the obviousness rejection over Makower '311 in view of Makower '875, i.e., Makower '875 does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. The "R" symbol is a single indicator, not first and second directional indicators offset from one another. In addition, the "R" does not comprise first and second indicators which form images that

connect to form a symbol.

Accordingly, claims 1-7, 12, 15, 16, 18-20, 23-25 and 37 are not obvious over Makower '875, and this rejection should be withdrawn.

Claim 21

Claims 21 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Makower '875. This rejection should be withdrawn for the same reasons as the obviousness rejection over Makower '311 in view of Makower '875, and the rejection over Makower '875, i.e., neither Makower '875 nor Makower '311 disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. The "R" symbol is a single indicator, not first and second directional indicators offset from one another. In addition, the "R" does not comprise first and second indicators which form images that connect to form a symbol.

Accordingly, claim 21 is not obvious over Makower '875 in view of Makower '311, and this rejection should be withdrawn.

Claims 15, 19, 20 and 22

Claims 15, 19, 20 and 22 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Armstrong (U.S. Publication No. 2002/0099431) in view of Makower '875. This rejection should be withdrawn for at least the same reasons as the obviousness rejection of claims over Makower '875, and over Makower '311 in view of Makower '875, namely Armstrong does not overcome the deficiencies of Makower '875, as described above. Again, Armstrong does not disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a

proper rotational orientation using an imaging device.

Accordingly, Claims 15, 19, 20 and 22 are not obvious over Armstrong in view of Makower '875, and this rejection should be withdrawn.

Claim 17

Claim 17 stands rejected under 35 U.S.C. Section 103(a) as being obvious over Makower '875 in view of Nash (U.S. Publication No. 2002/0032432). This rejection should be withdrawn for the same reasons as the obviousness rejection over Makower '875 in view of Makower '311, and the rejection over Makower '875, i.e., Nash does not overcome the deficiencies of Makower '875, as described above. Nash fails to disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. The "R" symbol disclosed in Makower '875 is a single indicator, not first and second directional indicators offset from one another. In addition, the "R" does not comprise first and second indicators which form images that connect to form a symbol.

Accordingly, claim 17 is not obvious over Makower '875 in view of Nash, and this rejection should be withdrawn.

Claims 1-6 and 24-26

Claim 1-6 and 24-26 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Flaherty (U.S. Patent No. 6,660,024) in view of Makower '875. This rejection should be withdrawn for at least the same reasons as the obviousness rejection over Makower '875 in view of Makower '311, and the rejection over Makower '875, i.e., Flaherty does not overcome the deficiencies of Makower '875, as described above. Flaherty fails to disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the

images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device.

Accordingly, claims 1-6 and 24-26 are not obvious over Flaherty in view of Makower '875, and this rejection should be withdrawn.

Claim 36

Claim 1-6 and 24-26 stand rejected under 35 U.S.C. Section 103(a) as being obvious over Ellis (U.S. Patent No. 6,416,490). This rejection should be withdrawn for at least the same reasons as the obviousness rejection over Makower '875, Makower '311, and the other cited prior art, i.e., Ellis does not overcome the deficiencies of the cited prior art, as described above. Ellis fails to disclose, suggest or otherwise render obvious an apparatus having first and second directional indicators wherein the images of the indicators connect to form the symbol when viewed from a proper rotational orientation using an imaging device. Ellis does not teach or suggest any symbols as a marker, nor indicators that form images that connect to form the symbol when viewed from a proper rotational orientation using an imaging device.

Accordingly, claim 36 is not obvious over Ellis, and this rejection should be withdrawn.

Conclusion

Any claim amendments which are not specifically discussed in the above remarks are not made for reasons of patentability, do not affect the scope of the claims, and it is respectfully submitted that the claims satisfy the statutory requirements for patentability without the entry of such amendments. These amendments have only been made to increase claim readability, to improve grammar, or to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

In view of the foregoing remarks, Applicant respectfully submits that all of the

Examiner's rejections have been overcome. Accordingly, allowance is earnestly solicited. If the Examiner feels that a telephone interview could expedite resolution of any remaining issues, the Examiner is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,

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